

**REMARKS****A. Status of the Claims**

Currently, claims 40-85, 87-90, 139 and 140 are under examination. Claims 42-85 are withdrawn from consideration. Claims 40, 41, 87-90, 139 and 140 stand rejected.

Claims 40 and 139 are rejected under 35 U.S.C. § 103(a) as being unpatentable over international application number WO 96/11712 to Kayyem et al. (“Kayyem”), in view of U.S. Patent No. 7,008,924 to Yan et al. (“Yan”) and Kabanov et al. (Adv. Drug Del. Rev. 30:49-610, 1998). The Examiner’s rejection is stated to be “made over the generic form of claims 40 and 139, not limited to any species.”

Claims 40, 41, 87-90, 139 and 140 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being allegedly unpatentable over claims 1, 7-24, 30, 31, 33-50, 57 and 59-61 of co-pending Application No. 10/591,486 (“the ‘486 application”).

Claim 40, 41, 87-90, 139 and 140 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting because the Examiner contends the claims are unpatentable over claims 1-3, 7-15, 29, 68-77 and 241-249 of copending Application 10/793,138 (“the ‘138 application”).

Claims 40, 41, 87-90, 139, and 140 also remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being allegedly unpatentable over claims 1-3, 7-15, 29, 68-77 and 241-249 of co-pending Application No. 11/073,307 (“the ‘307 Application”).

**B. Explanation of the Amendments**

In this paper, Applicants have amended claim 40 to recite that the biologic agent is selected from the group consisting of VEGF, botulinum toxin, a blocker of VEGF, antibodies

to VEGF, EGF, TGF- $\beta$ 1 and insulin. No new matter has been added by these amendments.

Support for the species of biologic agents recited in claim 40 is present in the specification as filed on pages 17, lines 7-8.

C. Election of Species

Claims 42-85 stand withdrawn from further consideration by the Examiner.

D. Claims 40 and 139 Are Patentable Over Kayyem in view of Yan and Kabanov.

Claims 40 and 139 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Kayyem et al. (WO 96/11712) in view of Yan et al. (U.S. 7,008,924) and Kabanov et al. (Adv. Drug Del. Rev. 30:49-610, 1998). Applicants respectfully traverse the rejection of generic claims 40, and 139. According to the Examiner, Kayyem “taught cell-specific delivery vehicles comprising oppositely charged polymer.”

The Examiner relies on Kayyem as providing a delivery vehicle to facilitate the delivery of the anti-tumor compound cyclophosphamide. Further in responding to Applicant’s arguments the Examiner states that “the nuclear localization function of the peptide would remain advantageous in facilitating delivery of cyclophosphamide to the nucleus, it’s site of activity.” Office Action, page 7. Applicants maintain their traverse of the Examiner’s ground of rejection, in view of the amendment to the claims made by Applicants which now recite specific peptide or protein biologics that all bind to cell surface receptors to initiate their biologic activity. None of these biologically active peptides or proteins therefore require localization to the nucleus as stated by the Examiner.

The combination of publications relied on by the Examiner does not teach or suggest Applicants’ claimed invention which is directed at the combination of charged

backbones, wherein the positively charged backbone is further covalently linked to specific amino acids as recited in the claims to deliver the specific peptides.

In view of the amendment to claim 40, and the Examiner's rejection of only claims 40 and 139, which depends from claim 40, Applicants respectively request withdrawal of this ground of rejection.

#### E. Obviousness-type Double Patent Rejections

The Examiner has provisionally rejected claims 40, 41, 87-90, 139 and 140 as allegedly being unpatentable on the ground of obviousness-type double patenting over claims 1, 7-24, 30, 31, 33-50, 57, and 59-61 of co-pending application no. 10/591,486. Further, claims 40, 41, 87-90, 139, and 140 are also provisionally rejected unpatentable due to obviousness-type double patenting over recited claims 1, 7-15, 29, 68-77 and 241-249 of co-pending application no. 11/073,307. Finally, claims 40, 41, 87-90, 139, and 140 stand provisionally rejected on the ground of obviousness-type double patenting over claims 1-3, 7-15, 29, 68-77 and 241-249 of co-pending application no. 10/793,138.

Applicants request to hold the non-obviousness type obviousness double patenting rejection in abeyance is noted by the Examiner who has maintained the rejection over the 10/793,138 application because the Examiner contends "the '138 application has the same effective filing date as the instant invention, and it's claims are broader than the instantly elected invention..." Applicants traverse this ground of rejection. The claims of the '138 application differ from the presently pending claims in that the '138 claims do not recite a negatively charged backbone as a component necessary in the composition. Moreover, it was not obvious that the requisite stability could be obtained to make a delivery system without this additional

negatively charged component. Accordingly, Applicants request that this ground of rejection be withdrawn.

### **CONCLUSION**

Based on the foregoing amendments and remarks, Applicants respectfully request reconsideration and allowance of this application.

### **AUTHORIZATION**

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. **50-3732**, Order No. 13720-105065US1.

Respectfully submitted,  
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